SECTION 2. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

2. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

JUN 20 2012

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT	Im-Able Ltd 2nd Floor, 92 Queens Drive Lower Hutt, New Zealand http://www.im-able.com/ Tel. +64-4-909 7304 Fax. +64-4-589 9533
OFFICIAL CORRESPONDENT	Sigi Caron MedTech Consultants, Inc. 2400 Via Carrillo Palos Verdes Estates, CA 90274 sigi@medtechconsultants.com Tel: (310) 377-3069 Fax: (310) 265-7618
TRADE NAME	Able-X
COMMON NAME	Non-powered exercise equipment
DEVICE CLASSIFICATION	Name: Non-measuring exercise equipment Regulation No: 890.5370 Product Code: ION Class: I Panel: Physical Medicine
PREDICATE DEVICE	▪ Encore Path's BatRac (TailWind) ▪ Accelerated Care Plus Corporation's OmniVR Virtual Reality Rehabilitation System

SUBSTANTIALLY EQUIVALENT TO:

The Able-X device is substantially equivalent in intended use and technological features to Encore Path's BatRac (TailWind), a Class I exempt device under 21 CFR §890.5370, and Accelerated Care Plus (ACP) Corporation's OmniVR Virtual Reality Rehabilitation System, a Class I exempt device under 21 CFR §890.5370.

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Able-X is an exercise system that uses virtual reality to promote therapeutic bilateral movement exercises through use of a wireless hand held game controller and computer games. The Able-X is comprised of a lightweight polymer handlebar with a wireless game controller mounted at one end and a fixed hand vertical hand grip at the other end of the bar. The wireless

controller communicates via a USB receiver dongle to a computer installed with therapeutic exercise games. Game play of the therapeutic exercises is controlled through the game controller and displayed in real-time on the computer screen. The Able-X therapeutic exercise games are provide on a CD or can be downloaded directly through the internet. The Able-X does not include a separate console and is intended to be operated directly through a user supplied computer that meets minimum processing and operating system requirements.

INDICATIONS FOR USE:

The Able-X is indicated for use by stroke patients undergoing upper limb rehabilitation to facilitate:

- Stroke rehabilitation by muscle re-education
- Maintaining or increasing range of motion

TECHNICAL CHARACTERISTICS:

The Able-X is a stroke rehabilitation system that uses a virtual reality based training system to promote therapeutic bilateral movement exercises. The Able-X is comprised of a lightweight polymer handlebar with a wireless game controller mounted at one end and a fixed hand vertical hand grip at the other end of the bar. The wireless controller communicates via a USB receiver dongle to a computer installed with therapeutic exercise games. Game play of the therapeutic exercises is controlled through the game controller and displayed in real-time on the computer screen. The Able-X is incorporated as part of a patient's overall physical therapy program by their healthcare provider.

PERFORMANCE DATA:

Testing confirms that the Able-X can be used according to its intended use and in an equivalent manner to the predicate devices.

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

The Able-X is substantially equivalent to the listed predicate devices with respect to their indications for use (intended use) and technical characteristics. The information and data provided in this 510(k) submission identifies no new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 20 2012

Im-Able Ltd
c/o Medtech Consultants, Inc
Sigi Caron
2400 Via Carillo
Palos Verdes Estates, California 90274

Re: K120783
Trade/Device Name: Able-X
Regulation Number: 21 CFR 890.5370
Regulation Name: Nonmeasuring exercise equipment
Regulatory Class: Class I
Product Code: ION
Dated: March 9, 2012
Received: May 10, 2012

Dear Sigi Caron:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K120783

Device Name: Able-X

Indications for Use:

The Able-X is indicated for use by stroke patients undergoing upper limb rehabilitation to facilitate:

- Stroke rehabilitation by muscle re-education
- Maintaining or increasing range of motion

Prescription Use __x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __x___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K120783

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